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PATENT Attorney Docket No. 350013-66

Serial No. 09/424,091 Filed: February 23, 2000

Title: IMMUNOLOGICAL METHOD Applicant: Kay, Richard

Group Art Unit No. 1644

Examiner: DeCloux, &

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Assistant Commissioner of Patents Washington, D.C. 20231

RESPONSE TO OFFICE ACTION

In response to the office action dated April 20, 2001 requiring an election, applicant elects, with traverse, the specific embodiment of the method of identifying an antigen-responsive T cell wherein the method comprises a method which quantitates the amount of specific T cell receptor RNA or the amount of T cell receptor RNA in a specific subset, as recited in claims 2-11, as set out in section 3 of the office action. Claims 1-11 and 18-20 are readable on the elected species.

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REMARKS

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In section 2 of the office action dated April 20, 2001, the Examiner has stated that the application contains claims directed to more than one embodiment of the generic invention and that these embodiments are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1. Applicant respectfully disagrees and would like to direct the Examiner to the PCT International Preliminary

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Examination Report and the Written Opinion of the International Preliminary Examining

Authority, wherein in both instances, a lack of unity of invention has not been found

(International Application No. PCT/GB98/01382). Applicant assert that the species are closely inter-related and are clearly not "distinct" and that restriction is therefore improper. Withdrawal of the election requirement is therefore requested.

Applicant also notes that the Examiner has stated, in part 1 of the office action dated April 20, 2001, that the first claim does not provide a technical feature that is distinguishes over Wigzell et al., (WO-A-94 14067), and applicant respectfully traverse this contention. The Wigzell et al. reference has been fully considered during the international application phase and furthermore, the present application, including claim 1, was found to be both novel and inventive, particularly in light of Wigzell et al. (please see earlier referenced International Preliminary Examination Report).

The claimed invention relates to <u>identifying</u> an antigen-responsive T cell within a population of T cells (typically where the <u>type</u> of antigen-responsive T cell is not previously known) by determining for <u>each of a plurality</u> of specific T cell receptors or subsets thereof whether the expression of a gene encoding a specific T cell receptor (or subset thereof) has increase <u>per specific T cell receptor-positive T cell</u> (or subset) compared to the expression of the said gene in a sample containing T cells which have not responded to the antigen.

The features of the present invention, are not disclosed or suggested in Wigzell et al.,

(WO-A-94 14067) for the following reasons. Firstly, the type of T cell receptor is already

known in Wigzell et al., (WO-A-94 14067) (i.e. V 2. 3) and therefore Wigzell et al. does not relate to a method of identifying a T cell receptor, since it has already been identified.

Secondly, there is no disclosure of determining for each of a plurality of specific T cell receptors

whether it is expressed in an antigen-responsive T cell. There is no motivation to do so in

Wigzell et al., (WO-A-94 14067), since the T cell receptor type involved in the disease (i.e.

responsive to the antigen) has already been identified (i.e. V-2. 3). Thirdly, in Wigzell et al.,

(WO-A-94 14067), there is no disclosure of measuring T cell receptors on a "per specific T cell Shows"

receptor-positive T cell" basis, but rather the measurements of V-2. 3 T cell receptor expression

are of the T cell population as a whole and not determined on a per specific T cell receptor
positive T cell basis, as recited in claim 1 in the instant application, for example.

Therefore, in light of the remarks above Applicant respectfully requests that the Examiner withdraw the election requirement and further contends that the present application does indeed provide technical features that are distinguished over Wigzell et al. and, additionally, does not lack Unity of Invention. In any event, a favorable action is requested on generic claims 1 and 18-20, and elected species claims 2-11.

The Commissioner is hereby authorized to charge any additional filing fees under 37 C.F.R. § 1.16, or application processing fees under 37 C.F.R. § 1.17, which may be required now or during the pendency of this application, or credit any overpayment to Account No. 16-2230. A duplicate copy of this sheet is enclosed.

Applicant requests a one month extension of time to respond to the Office Action of April 20, 2001. Applicant encloses herewith our check number 22937 in the amount of \$110.00 in payment of the one month extension fee.

Dated: June 20, 2001

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